



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

February 4, 2002

VIA FEDERAL EXPRESS

Michael Clifton
Import Manager
Storck USA L.P.
500 N. Michigan Ave.
Chicago, IL 60611-3704

WARNING LETTER
(02-ATL-18)

Dear Mr. Clifton:

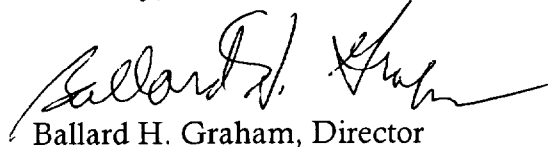
On January 25, 2002, FDA collected a sample of Werther's Original Hard Candies, Entry 100-0328398-2, in accordance with our Notice of Sampling dated January 4, 2002. This product had been offered for import into the United States by your firm on January 5, 2002. Our Consumer Safety Technician found that [REDACTED] cartons from this entry had been distributed into commerce without a proper release from us. This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Your response should be sent to Sheryl R. Cruse, Compliance Officer, at the above address noted in the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham", with a long horizontal flourish extending to the right.

Ballard H. Graham, Director
Atlanta District